Clinical Research

Novel Use of Active *Leptospermum* Honey for Ringed Fixator Pin Site Care in Diabetic Charcot Deformity Patients

Alexander L. Lazarides, MD, Kamran S. Hamid, MD, MPH, and Michael S. Kerzner, DPM

Abstract: Introduction. *Open reduction with external fixation (OREF) utilizing fine wire ringed fixators for correction of Charcot deformity has gained popularity over the past decade. Pin site infections are a well-documented complication of external fixation as well as a driver of escalating health care costs. We aimed to demonstrate the safety and efficacy of a novel method of pin site care utilizing active* Leptospermum *honey–impregnated dressings (MediHoney) in diabetic patients undergoing deformity correction with OREF.* Methods. *Twenty-one diabetic patients with Charcot deformities of the lower extremity were prospectively enrolled and followed for pin site complications following OREF for deformity correction. Active* Leptospermum *honey dressings were applied at metal-cutaneous interfaces at the end of the OREF procedure and replaced weekly for a total of 8 weeks. Patients were monitored for pin site infections from the time of surgery until external fixator removal. Sixteen consecutive patients receiving standard OREF for Charcot deformities were evaluated retrospectively to serve as a control group.* Results. *Of the 21 enrolled patients, 19 underwent OREF and followed up throughout the study period. Treated patients had a mean age of 58.5 years and mean body mass index measuring 33.3 kg/m^2 as documented prior to surgery. The 15 patients with hemoglobin A1c labs drawn in the 3 months preceding surgery averaged 7.5. Fixators were removed at an average of 12.1 weeks after adequate bony healing. Of the 244 pin sites in 19 patients, 3 pin sites (1.2% of pins) in 2 patients (10.5% of patients) showed evidence of superficial infection. All infections resolved with oral antibiotics. Infection rates were significantly reduced when compared to the standard care control group.* Conclusions. *Pilot data in a prospectively collected case series demonstrate safety and efficacy of active* Leptospermum *honey–impregnated dressings when used for fine wire ringed fixator pin site care in diabetic Charcot deformity patients. Further investigation in the form of a prospective randomized controlled study is warranted to demonstrate the potential value of this novel intervention.*

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DOI: 10.1177/1938640017709907. From the Department of Orthopaedic Surgery, Duke University Medical Center, Durham, North Carolina. Address correspondence to: Alexander L. Lazarides, MD, Department of Orthopaedic Surgery, Duke University Medical Center, 4709 Creekstone Drive, Durham, NC 27703, USA; e-mail: all24@duke.edu.

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Pin site infections are a well-documented complication of external fixation with infection rates of up to 40%.[1-6] In the past decade, open reduction with external fixation (OREF) for correction of deformity in diabetic patients with Charcot deformity of the foot and/or ankle has gained popularity. Finkler et al[2] demonstrated a 20.8% pin site infection rate in a large, prospectively collected series of 283 diabetic patients undergoing single-stage correction of Charcot foot deformity with static fine-wire circular external fixation and a minimalist pin care protocol. In their series, there was no correlation identified between body mass index or osteomyelitis and pin site infection, though there was a statistically significant correlation between patients with elevated hemoglobin A1c levels and pin site infections.

The OREF technique with circular external fixator for deformity correction and limb salvage has demonstrated excellent results with costs comparable to that of transtibial amputation.[3] This technique has shown tremendous success, even in the face of significant osteomyelitis and deformity.[7,8] The rising popularity of this treatment modality has resulted in an increased interest in new methods for prevention of pin site infections.

Active *Leptospermum* honey (ALH) is a monofloral honey derived from the Mānuka tree in Australia and New Zealand. ALH has demonstrated antibacterial properties that have been investigated at the cellular level,[9-19] in adult ulcers and wound care[20-29] and more recently, for wound management in susceptible populations such as neonates.[21,30,31]

With the growing burden of pin site infection disease, there is increasing interest in novel treatment modalities for pin site complication prevention, particularly in the vulnerable diabetic population. To date, there have been no studies examining ALH's utility as a preventative measure against pin site infections. We hypothesized that a simple ALH-impregnated dressing (MediHoney) would provide a safe and effective means to dress pin sites postoperatively and yield low pin site infection rates in diabetic patients undergoing OREF for Charcot foot or ankle deformity.

Methods

Patient Enrollment

After obtaining institutional review board approval, 21 diabetic patients with Charcot deformities of the lower extremity provided informed consent and were prospectively enrolled and followed for pin site complications following OREF for deformity correction between January 2014 and July 2015. Patient demographic characteristics, including age, hemoglobin A1c (HgA1c), and body mass index (BMI) were documented prior to surgery.

Operative Technique

A single surgeon performed all surgeries with a consistent surgical technique used for OREF in all cases. The patient was prepped and draped in sterile fashion with appropriate preoperative timeouts performed. Minimalist incisions were made to create exposure for the requisite deformity correction osteotomies. Utilizing fluoroscopic guidance K-wires were placed for referencing purposes. Bony resection was then performed with an oscillating saw. Next, the static circular frame was placed over the extremity with a stack of towels supporting the calf and elevating the leg in space within the rings. Fine wires or half pins, as necessary, were applied and tensioned in the tibia, followed by olive wires in the calcaneus and smooth wires through the forefoot at the base and mid shaft of the metatarsals grabbing at least 3 metatarsals with each of the smooth wires. These were then rigidly tensioned to apply compression at the osteotomy site. Final position and appearance was confirmed under fluoroscopy with good clinical alignment of bone as deemed by the surgeon. Closure was completed in an interrupted fashion. Care was taken to avoid tensioning of the skin.

Pin Care and ALH Dressings

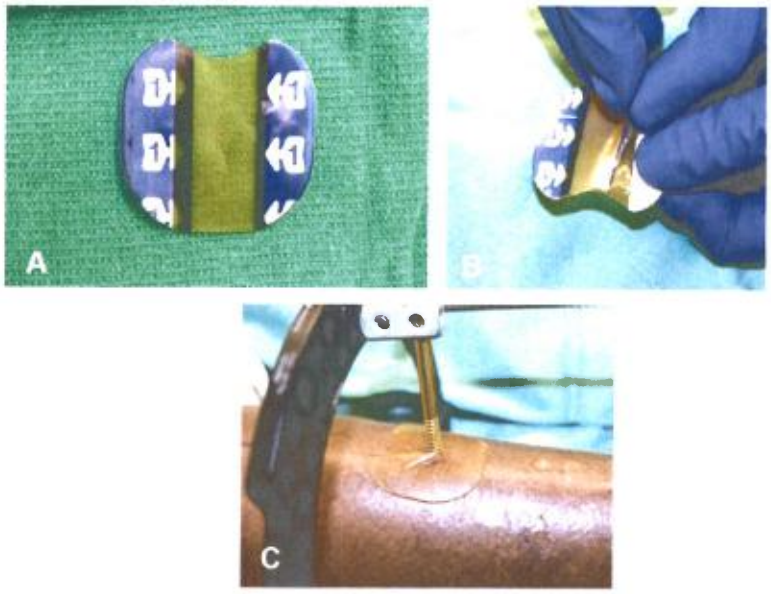
At the end of the procedure, MediHoney patches were applied over the pin sites as per the manufacturer's directions; dressings were placed such that the metal-cutaneous interface was surrounded by the patch, with the adhesive surface in contact with the skin (see below). Incisions were dressed in nonadherent dressings and the entire construct was wrapped in bulky soft dressings. ALH dressings were applied at metal-cutaneous interfaces at the end of the OREF procedure and replaced weekly after cleansing with dilute peroxide solution (ie, standard pin care) for a total of 8 weeks (Figure 1). Cleansing was performed by taking 1 part normal saline and 1 part hydrogen peroxide and mixing together to form a cleansing solution. Sterile cotton tip applicators were used to swab the solution around pin sites. This was performed on the third postoperative day and daily until removal of the external fixation construct. Patients were monitored from the time of surgery until external fixator removal for pin site infections. All patients received preoperative prophylactic antibiotics for the perioperative period.

Outcome Measures

The primary outcome measure was clinical pin site infection from the time of surgery until external fixator removal. All pin sites, including thin wire and olive wire, were evaluated for pine site infection. Pin site infection was defined as persistent purulent drainage or significant erythema about the pins for the period of external fixator use.

Figure 1.

(A) Active *Leptospermum* honey–impregnated dressing out of package. (B) Adhesive component exposed. (C) Dressing applied at metal-cutaneous interface at the end of the open reduction with external fixation procedure.



Treatment of suspected infection was initiated when the patient demonstrated signs of infection and consisted of empiric treatment with a first-generation cephalosporin. No patients were lost to follow-up. Secondary outcome measures included time to removal of external fixator, removal of external fixator less than 8 weeks after its application (defined as "early removal"), and additional procedures.

Retrospective Control Group

Sixteen consecutive diabetic patients with Charcot deformities of the lower extremity were retrospectively reviewed for comparison as a control group to evaluate for pin site complications following standard OREF for deformity correction between November 2015 and July 2016. These patients did not receive ALH dressings, but otherwise received standard pin care as indicated above. Patient demographic characteristics, including age, HgA1c, and BMI were collected from the time of surgery, and patient records were evaluated over the course of external fixator application for evidence of infection.

Statistical Analysis

Continuous data were normally distributed when skewness was tested and normal quantile plots were visually assessed. Student *t* test was used to assess dichotomous predictors with continuous outcomes. Associations between dichotomous outcomes and dichotomous predictors were tested with Fisher's exact test. Statistical analysis was performed by an individual with an advanced degree in biostatistics. JMP 12 software (SAS Institute, Cary, NC, USA) was used for analysis.

Results

Twenty-one patients were prospectively screened and enrolled; of the 21 patients, 19 underwent OREF and followed up throughout the study period. Both excluded patients were deemed too medically fragile for surgery during preoperative cardiac evaluation, and both patients were subsequently excluded, as they did not undergo surgery. Table 1 summarizes the demographic data of the prospective ALH study group and the retrospective standard care control group. Within the ALH study group, the mean age of treated patients was 58.5 years (range 39-74 years) with a mean BMI of 33.2 kg/m^2 (range 21.1-42.7 kg/m^2). There were 15 males and 4 females. Fifteen patients had a HgA1c drawn before surgery with an average of 7.5 (range 5.4-10.5). Sixteen consecutive diabetic patients undergoing OREF for Charcot deformity were retrospectively reviewed to serve as a control comparison group. The mean age of treated patients was 58.8 years (range 38-71 years) with a mean BMI of 36.7 kg/m^2 (range 24-46 kg/m^2). There were 8 males and 8 females. All patients had a HgA1c drawn before surgery with an average of 7.1 (range 5.6-11.7). There were no statistically significant differences in baseline characteristics between the 2 study groups.

Within the ALH study group, thin wire frames were removed at an average of 12 weeks (range 6-16 weeks). Of the 244 pin sites in 19 patients, 3 (1.2%) pin sites in 2 (10.5%) patients showed evidence of infection during the time the frames were on the patient (Figure 2). The patients with pin site infections were treated with oral antibiotics and infections resolved without incident. All patients achieved clinically and radiographically adequate alignment and no patients required early pin removal prior to the expected 8-week course or debridement procedure related to pin sites, though 1 patient completed an uncomplicated treatment course by 6 weeks demonstrating satisfactory osseous healing with subsequent removal of the external fixator at that time.

By comparison, within the standard care control group, thin wire frames were removed at an average of 10 weeks (range 1.5-15.5 weeks). Of the 217 pin sites in 16 patients, 16 (7.4%) pin sites in 9 (56.5%) patients showed evidence of infection during the time the frames were on the patient. This was statistically

Table 1.

Demographic Data by Pin Site Care.

	Standard (n = 16)	ALH (n = 19)	*P*
Pin sites (per patient), n	13.5 (total: 217)	12.8 (total: 244)	.4
Sex, n (%)			.09
Male	8 (50)	15 (79)	
Female	8 (50)	4 (21)	
Race, n (%)			.7
White	10 (63)	14 (74)	
Black	6 (38)	5 (26)	
Age, years, mean (range)	58.8 (38-71)	58.5 (39-74)	.9
BMI, kg/m^2, mean (range)	36.7 (24-46)	33.3 (16.3-61.6)	.3
Hemoglobin A1c, mean (range)	7.1 (5.6-11.7)	7.5 (5.4-10.5)	.5

Abbreviations: ALH, active *Leptospermum* honey; BMI, body mass index.

Figure 2.

An infected pin site is demonstrated. Despite application of the active *Leptospermum* honey impregnated dressings, 2 patients developed a pin site infection with external fixation. The authors recognize that the pins were placed through the incision sites and that this may be suboptimal; however, this is the best representative clinical photo available.

significant ($P < .01$) and higher when compared with the ALH study group.

The patients with pin site infections were treated with oral antibiotics. While most infections resolved without incident, 3 patients required early pin removal or debridement procedure related to pin sites; 2 of these patients ultimately required a below the knee amputation. Both patients required amputation secondary to pin site infection progressing to uncontrolled osteomyelitis. There were no statistically significant differences in time to frame removal and additional procedures between the 2 study groups. A comparative summary of clinical outcomes is included in Table 2.

Discussion

Pin site infection is a challenging and commonly encountered complication of external fixation. OREF utilizing fine wire ringed fixators has recently gained popularity as a cost-effective and well-tolerated strategy for the management of Charcot deformity in the ankle. As the utilization of this treatment modality grows, the need for novel methods of prevention of pin site infection is of increasing importance. Additionally, while some studies suggest that some patient factors such as HgA1c and osteomyelitis may correlate with increased rates of pin site infection, there do not appear to be clear predictors of infection in the management of this disease process, making risk stratification difficult.[2,32] In this prospective case series, we demonstrate the safety and efficacy of ALH-impregnated dressings when used for fine wire ringed fixator pin site care in diabetic Charcot deformity patients, with significantly reduced rates of pin site infection when compared with a retrospective control group.

The study by Finkler et al[2] on pin tract infection in Charcot foot offers the best option for comparison with our present study. In their series, as in ours, erythema and drainage resolved in all patients with local pin care and empiric oral antibiotic therapy. No wires were removed prematurely, and all infections resolved following removal of the circular external fixator at the scheduled time for removal. Unlike their study, in which HgA1c was correlated with higher rates of infection, the current investigation was unable to demonstrate a statistically significant impact of HgA1C on rates of infection ($P = .5$). In 283 patients, Finkler et al[2] demonstrated an infection rate of 20.8%; our study demonstrated an infection rate of 10.5% in 19 patients with 244 pin sites, though it is not possible to compare these 2 groups without proper adjustment. While our study has a substantially smaller sample population, we believe that the presented pilot data have the benefit of being prospectively conducted and indicates that ALH dressings may be a viable and effective means of reducing pin site infection rates.

A wealth of research has been produced looking at novel methods of reducing pin site infection, including experimentation with external fixator pin materials and coatings.[33] With regard to pin materials, titanium and copper have demonstrated potential benefit in reducing pin site infection rates.

Table 2.

Clinical Outcomes.

	Standard (n = 16)	ALH (n = 19)	*P*
Infected pin sites, n	16	3	<.01
Time to frame removal, weeks, mean (range)	10.4 (1.5-15.5)	12.1 (6.1-16.0)	.1
Frame removal prior to 8 weeks, n	3	0	.09
Additional procedures, n	3 (2 below-knee amputations, 1 wound debridement)	0	.09

Copper-titanium alloys, specifically, have been shown to have superior efficacy over titanium alone. A study by Shirai et al[34] demonstrated that, in rabbit models, pins constructed using such alloys had significant antibacterial activity and lowered rates of infection. However, despite its antibacterial properties, copper is known to be toxic to human tissue in high concentrations, limiting its potential use. Similarly, a number of coatings have been examined.[33] A simple solution has been to use antibiotic impregnated implants. Gentamicin-impregnated implants, in particular, have shown potential, with some studies demonstrating 90% reduction in rates of osteomyelitis with intramedullary implants as compared with only a 15% reduction with systemic antibiotics.[35] However, these are not without toxicity and the concern for the development of antibiotic resistance. Few studies have examined antibiotic impregnated pins in the context of external fixation. Other options include antiseptic coated implants, namely chlorhexidine and iodine. Both antiseptics have demonstrated significant reductions in colonization rates of *Staphylococcus aureus* and *Escherichia coli*.[36,37] Despite the clear ability to reduce rates of bacterial infection, these materials are limited by their significant cytotoxic effect on tissue and inhibition of osseointegration. Overall, these are promising developments in prevention of pin site infection; however, many of these developments are cost prohibitive, have unwanted side effects and consequences, or fail to reduce pin site infection rates in a significant manner.

Use of ALH dressings have the benefit of being safe and efficacious while maintaining cost consciousness. Previous studies have demonstrated the favorable characteristics of this medical-grade honey on wounds. The beneficial antimicrobial, physiologic, and biochemical characteristics are well documented.[12,13,24,38,39] In the presence of medical-grade honey, bacteria preferentially degrade glucose in the honey, sparing the tissue from degradation and producing lactic acid as a byproduct (which is additionally prohibitive of bacterial activity). Overall, this has the benefit of sustained bactericidal activity and a favorable environment for tissue regeneration without the risk of developing antibiotic resistance. Our study is unique from prior investigations as it specifically tackles a method of reducing pin site infection in a high-risk patient population with Charcot deformities using a naturally occurring medical-grade honey with low cost and few side effects.

Despite its prospective nature, there are limitations to this investigation. Our sample size was limited, enrolling only 19 patients with 244 pin sites in this study; while we did employ a control group, this group consisted of only 16 consecutive patients examined in a retrospective manner. This is not unexpected as thin wire ringed external fixation is a complex procedure and not necessarily routinely used for Charcot foot reconstructions. despite this, we feel that the significance of the results remains relevant and clinically informative. Unfortunately, there are inherent flaws in having a prospective experimental group compared with a retrospective control group. Namely, such a study design introduces the possibility of recall and selection bias with the potential for differences in standardization of treatment that may affect the outcomes. Additionally, patients were instructed in care of the pin sites, but regulation of home pin care was not possible and variations could have existed therein. Nonetheless, despite the limited enrollment, our results speak to the safety and efficacy of medical grade honey for pin in a pilot study.

This prospectively collected case series provides pilot data that demonstrates safety and efficacy of ALH impregnated dressings when used for fine wire ringed fixator pin site care in diabetic Charcot deformity patients. Further investigation in the form of a large-scale randomized control study is warranted to demonstrate the potential value of this novel intervention.

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